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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/599,125

09/20/2006

Ana Belen Bueno Melendo

X-16772

4566

25885 7590 03/17/2009

ELI LILLY & COMPANY

PATENT DIVISION

P.O. BOX 6288

INDIANAPOLIS, IN 46206-6288

EXAMINER

MCDOWELL, BRIAN E

ART UNIT

PAPER NUMBER

1624

NOTIFICATION DATE

DELIVERY MODE

03/17/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

Office Action Summary	Application No.		Applicant(s)	
	10/599,125		BUENO MELENDO ET AL.	
	Examiner		Art Unit	
	BRIAN MCDOWELL		1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6 and 9 is/are pending in the application.
- 4a) Of the above claim(s) 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/20/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION
RESPONSE TO ELECTION/RESTRICTION

Applicant's election with traverse of Group I and elected specie in the reply filed on 2/23/2009 is acknowledged. However, the election of specie requirement is removed. The traversal is on the ground(s) that groups I and II share a special technical feature. This is not found persuasive because at the time of examination, the instant application did not have a special feature as evidenced in the previous office action. Thus, the restriction requirement was proper and the inventions were shown to lack unity via *a priori*. Consequently, Applicant had elected group I for examination purposes, not group II (wherein R³ = piperazin-2-yl).

The requirement is still deemed proper and is therefore made **FINAL**.

Claim 9 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

This application contains claims drawn to an invention nonelected with traverse in the reply filed on 2/23/2009. A complete reply to this action must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

An action on the merits of claims 1 and 6 is contained herein.

Priority

This application receives the priority date of 4/22/2004, drawn to provisional application 60/564538.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 8, and 13 of copending Application No. 10/599129. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 2, 8, and 13 in the copending application recite identical definitions and limitations for R¹ and R² and further provides definitions and limitations for R³ where R³ is pyrrolidin-2-yl, which provides

homologous subject matter with respect to the substituted piperidin-2-yl and pharmaceutical compositions of formula I in the instant claims.

The MPEP § 2144.09 states that *compounds which are homologs, differing regularly by the successive addition of the same chemical group, e.g., by -CH₂- groups, are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties.* {See *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977)}.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

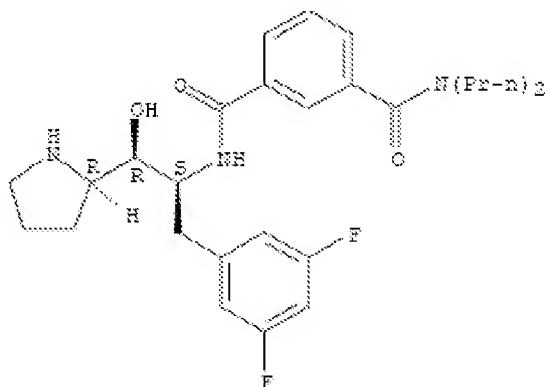
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

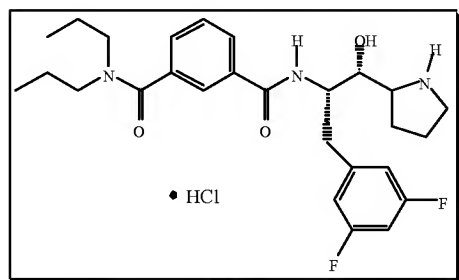
Claims 1 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cumming *et al.* (WO 05/016876-document mentioned in IDS).

The instant claims are drawn to substituted or unsubstituted piperidin or tetrahydropiperidin-2-yl compounds of the formula I and simple compositions thereof used for the treatment of Alzheimer's disease.

Cumming *et al.* teach the following compound below:



wherein X = -CH-; Y = -CR¹¹, where R¹¹ = -H; Q = CR¹², where R¹² = -H; R⁶ = -propyl; and R⁷ = -propyl); R² = -benzyl, optionally disubstituted with fluoro; and R³ = unsubstituted pyrrolidin-2-yl [see p. 39, example 1A; HCl salt - p. 17, lines 26-30; also



in priority document US 60/493,987 - p. 33, example 2; and pharmaceutical compositions - p. 6, lines 11-13].

This document also mentions that these compounds are applicable as BACE-1 inhibitors and are consequently useful in the treatment of disorders such as Alzheimer's disease (see abstract).

The instant claims may embrace the same compound above, except R^3 = unsubstituted piperidin-2-yl. As mentioned previously in this office action (see ODP rejection), the two species are considered homologs.

The MPEP § 2144.09 states that *compounds which are homologs, differing regularly by the successive addition of the same chemical group, e.g., by -CH₂- groups, are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties.* {See *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977)}.

In summary, applicant is taking a well-known compound that is described in the literature and executing a simple modification (substituting a piperidine for a pyrrolidine). Both compounds have the same utility, and it would be expected that based on the teaching by Cumming, that a compound with similar biological activity would have been obtained upon this simple modification.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRIAN MCDOWELL whose telephone number is

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(571)270-5755. The examiner can normally be reached on Monday-Thursday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BM

/James O. Wilson/

Supervisory Patent Examiner, Art Unit 1624